

## **PUBLIC HEALTH COUNCIL**

A regular meeting of the Massachusetts Department of Public Health's Public Health Council was held on Wednesday, April 9, 2008, 9:00 a.m., at the Department of Public Health, 250 Washington St., Boston, Massachusetts in the Henry I. Bowditch Public Health Council Room. Members present were: Chair John Auerbach, Commissioner, Department of Public Health, Dr. John Cunningham, Dr. Michèle David, Dr. Muriel Gillick, Mr. Paul J. Lanzikos, Mr. Denis Leary, Ms. Lucilia Prates Ramos, Mr. José Rafael Rivera, Dr. Meredith Rosenthal, Mr. Albert Sherman, Dr. Alan C. Woodward and Dr. Barry S. Zuckerman. Ms. Caulton-Harris, Mr. Harold Cox, and Dr. Michael Wong were absent. Also in attendance was Attorney Susan Stein, First Deputy General Counsel filling in as Counsel as Attorney Donna Levin, DPH General Counsel was absent.

Chair Auerbach announced that notices of the meeting had been filed with the Secretary of the Commonwealth and the Executive Office of Administration and Finance. He further announced that the docket items would be heard in a different order. Items follow below in the order heard. Council Member Sherman was welcomed back after his successful kidney transplant operation.

### **RECORD OF THE PUBLIC HEALTH COUNCIL MEETING OF JANUARY 9, 2008:**

A record of the Public Health Council Meeting of January 9, 2008 was presented to the Public Health Council for approval. Dr. Alan Woodward, Council Member, noted corrections that were needed to the minutes: "On page 6, 4<sup>th</sup> line of the minutes, there is a typo; the organization should be JACHO, not JCAH. And further on page 9, Dr. Woodward is listed both in favor and abstaining; he abstained. He said further, "It was amended with two things; one was the tobacco language and the other amendment, was the fact of just having telephone backup available to a physician from the nurse practitioner, and that was described in the third paragraph down but not on the bottom of page 9 – minor." Council Member Paul Lanzikos also pointed out that he voted in favor of the final regulations. Dr. Alan Woodward moved for approval of the minutes of January 9, 2008 with the above corrections. After consideration, upon motion made and duly seconded, it was voted unanimously to approve the January 9, 2008 record with corrections as noted above by Dr. Woodward and Mr. Lanzikos. The record was distributed to the members prior to the meeting for review.

## **PROPOSED REGULATION:**

### **Informational Briefing on Proposed Amendments to Determination of Need Regulations – 105 CMR 100.000 et seq. (original licensure of hospitals, physician exemption letters, and section 308 exemption requirements):**

Chair Auerbach made introductory remarks regarding the DoN amendments. He noted in part, "We have spent a number of months trying to be responsive to the request of the Council, the new Council Members, to reconsider how we think about the Determination of Need Program. We have also not been doing that reconsideration in isolation. There are many other leaders and entities that are also considering this, and I want to, at this point, pay particular attention and recognition to the work that Senate President Therese Murray has provided in terms of this particular issue and the work that she has done with her staff, in the last month, to highlight the importance of rethinking the laws and the regulations on health care. I am delighted that joining us this morning is Mr. David Seltz, Senior Policy Director for the Senate President. He has been in communication with the Department as we developed this presentation and he will be available to answer questions..."

Dr. Paul Dreyer, Director, Bureau of Health Care Safety and Quality, accompanied by Attorney Carol Balulescu, Deputy General Counsel, Office of the General Counsel, presented the informational briefing on proposed DoN Amendments to the Council. Dr. Dreyer presented the historical facts about the DoN program, with its inception in 1972 to health planning in 1975 with the federal Health System Agencies... "To me", he said, "the seminal event was the introduction of DRG reimbursement of hospitals in 1983, which changed incentives, so hospitals received a fixed payment by DRG (Diagnosis Related Group) regardless of the actual length of stay of a patient. In 1986, the federal program was repealed and there was no more funding for state health planning...In 1988, state legislative reform with Chapter 23, which deregulated acute care beds and outpatient services. In 1990, a linkage requirement was added to the DoN Regulations requiring a community contribution to capital projects...In 1993 a public hearing requirement was added to the regulations in cases of hospital transfers of ownership...In 1997 Cardiac Catheterization was deregulated and done through licensure instead of DoN and the same for bone marrow transplants in 1998."

In summary, Dr. Dreyer stated, "...I think this is a fair description of the literature, the jury is out on whether DoN has been effective or not. The most recent literature looked at states with and without DoN with respect to mortality for cardiac surgery. What you observe in states that deregulated was the number of cardiac surgery programs grew much more rapidly than in states that maintained cardiac surgery. Some initial studies found higher mortality in those states that had deregulated. Later attempts to replicate those findings failed to support the relationship. The later studies found, although the number of services did grow, there wasn't a relationship between mortality and deregulation." During his slide presentation Dr. Dreyer showed a slide that said U.S. inpatient hospital days, age adjusted, per 1,000, dropped from 1980 to 2004 from around 1300 inpatient days per thousand to under 600 - Age Adjusted utilization dropped by more than half. Council Members Drs. Woodward and Rosenthal said it was due to DRGs and Dr. Dreyer agreed. In response to questions by Dr. Zuckerman, Dr. Dreyer, said, "It is clear that we have the highest health care costs in the nation; but, as we have seen from this slide, our utilization of hospitals is about the same as the nation, and we have probably fewer beds than the rest of the nation...To me the question is, what is driving U.S. Health Care costs; and so, here is an international comparison, which shows the U.S. compared to the OECD, which is essentially advanced countries with developed economies."

Dr. Dreyer further stated, "One might argue that we have seen a public policy success here –excessive hospital utilization was identified as a driver of costs in 1974. Since, then we have seen a dramatic decline in U.S. hospital utilization so that now we are below the mean of the OECD with respect to beds, and inpatient utilization. The only flaw in the argument, of course, is that costs haven't gone down at all. We all know they have gone up dramatically. I think there is lots of room for considerable discussion on these points, but let me go on to where we are now and bring us back to DoN. These are the current DoN mandates. With respect to acute care hospitals, beds have been essentially deregulated. In 1998, hospital beds were removed from the definition of substantial change in service. The addition of outpatient services were also deregulated so that anyone could build any sort of outpatient facility that they wanted, with the exception of ambulatory surgery, without DoN. With respect to capital projects, acute care facilities in excess of \$12,516,300 and Non-acute care facilities in excess of \$1,335,072. Changes of ownership for hospitals and ambulatory surgery centers are required to file.

Dr. Zuckerman inquired about beds being deregulated and the acute care facilities adding new beds. It was clarified that "Acute care beds are still regulated in so far as they trigger expenditures in excess of the 12.6 million dollars but neither the need for or the number of beds is considered. Dr. Dreyer noted, "...This is still a murky area and it makes it difficult to analyze projects. In

the capital projects what we have done, we have essentially used a test of reasonableness. Does what the hospital proposes to do make sense? Is it more or less sensible?"

Discussion continued by the Council members. Dr. Dreyer said in part, "I think the legislature was clear in its intent that we not look at beds because they, in fact, removed acute care beds from the definition of substantial change in service...It was part of an overall rate deregulation. It was an experiment in letting the market play a much larger part in how hospitals operate and so from that global perspective, you might say, not considering beds would be consistent with that effort."

Chair Auerbach added, "I think you have hit the point that has become the most confusing for the new Council members in doing the DoN reviews because the Council Members in looking at large capital expenditures, wanted to talk about need, and to talk about, was this a justified capital expenditure based upon need. Then we would say, you can't consider need because we don't have the authority for you to do that, you just have to look at cost, and they found that illogical and not productive....We only have the authority given to us by the Legislature so we need to do this in partnership with the Legislature and understand their intention which is partly why we are glad that the Senate President and Mr. Seltz are involved in this discussion with us."

Dr. Zuckerman inquired about the need for more beds in case of an epidemic like the flu. Dr. Dreyer said we need more beds and Chair Auerbach elaborated, "...The Department of Public Health has multiple roles. One is participating in the Public Health Council, which has specific authority given to it by the legislature. The Department of Public Health has vested in it the responsibility of looking more broadly at health care trends, issues of major concern for quality to the residents of the Commonwealth...Part of the issues is determining both what do we need, and to do it well, and those are certainly discussions we can have. Dr. Zuckerman further asked, "Is there a role for the Council in its relationship with the Department, to understand what are the tasks that need to be done?" Chair Auerbach replied, "Yes, I would say that the Council has within its authority the ability to identify need and make recommendations..."

Dr. Dreyer continued his slide presentation on the DoN current mandates: "Currently there is no aggregate need for nursing home beds statewide so the Department is not accepting applications until 2010. DoN continues to process DoNs for replacement and renovation which only come to the Council if there is an objection from a Ten Taxpayer Group. DoN looks at original licensure which is triggered by transfer of ownership. The process requires a public hearing. With respect to innovative services and new technology DoN continues to regulate ECMO Air Ambulance, open heart surgery, MRIs, new natal intensive

care units, organ transplantations; PET and radiation therapy which go before the Council."

In closing remarks, Dr. Dreyer stated, "Is this a time to reconsider health care regulations? I think we would argue that there are three primary reasons to raise this question now. One is Health Care Reform has changed the landscape and it has focused everyone's attention on really two issues. One issue is access and we have heard a great deal in the Council about access to services that may be a problem, even for those with insurance. Add shortages in primary care. We are aware of shortages in obstetrics and gynecology and in other clinical specialties, and of course, the last and probably major point is that costs continue to grow at an alarming rate despite the declines in hospital utilization that we have seen previously. There are also changes in the hospital environment. There are 50 fewer hospitals since 1978. A few large teaching hospitals or organizations are expanding to new locations in the State. The community hospitals are concerned with the growing competition...Numerous leaders have raised the need to consider health care oversight. The new Cost and Quality Council created by Chapter 58 has asked us to look at DoN. The new EOHHS Secretary created the Healthy Massachusetts Compact to take quick action steps on Health Care Costs and Quality, and the Public Health Members have certainly expressed their concern about how to think about the best way to think about need when they consider large DoN capital projects; and, finally Senator Murray has proposed a number of legislative reforms, including the regulation of Ambulatory Surgery Centers, which would bring them into our purview..."

Council Member Paul Lanzikos, inquired about the Healthy Massachusetts Compact. Chair Auerbach explained it to the Council. He said in part that the Compact has established five specific areas of activity: Pay-for-Performance priorities, streamlining administrative costs, focusing on the elimination of serious adverse incidents in clinical settings and promoting wellness and chronic disease management. The Department of Public Health is charged with staffing the committee that focuses on wellness and chronic disease management. Chair Auerbach suggested that maybe he could have someone from the Division of Health Care Finance and Policy come to a Council meeting to provide more information on their role in the Massachusetts Compact.

During his presentation, Dr. Dreyer mentioned the Senate President's bill 2526 which he said "seeks to strengthen the DoN process to help maintain standards of quality and protect existing community providers and ensure the economical and equitable deployment of health care resources across the Commonwealth." He noted three of the proposals relevant to the DPH/Council: (1) requirement that ambulatory surgery centers be considered as clinics for the purposes of licensure; (2) requirement of the registration of so-called physician letters of

exemption and prohibition of their transferability and it voids any unused letters; and (3) the requirement that providers annually testify to the Health Care Quality and Cost Council on their cost drivers, including specific testimony on how capital and technology investments affect overall cost.

Mr. David Seltz, Senior Policy Director, Senate Present's Office was present and answered some questions by Council members. Dr Alan Woodward, asked in part, "Is the Senate President and others, looking at, from a macro view, the whole DoN process, and the significance of the DoN process and centralized planning versus premarket forces and, obviously, we are seeing transitions within the health care system, a lot of it centralized into centers that are more and more expensive, as far as providing care. Is there any discussion? I understand these specific recommendations but looking forward – is there an interest in having the broader discussion?" Mr. Seltz replied in part, "Absolutely, the Senate President is concerned about the deliberation of these very expensive capital projects and wondering what impact that has on overall cost. She has proposed a couple of common sense things [in Senate bill 2526]...We are willing to work with the Council to discuss those and in order to strengthen the role of the Council...The Senate President views these as first steps..."

Chair Auerbach noted, "Thank you for your leadership on this, and please relay our appreciation to the Senate President for our recognition of the extraordinary leadership she has played in terms of raising these issues and opening up the process for discussion on topics that haven't been considered or talked about for many years when, clearly, there is a need to do so. We look forward to working with you.

In regard to the DoN regulations being proposed Dr. Dreyer, said, "The regulations before you have a couple of components. The first is to ensure that hospital beds in new locations are reviewed for duplication and impact, and what this is about is making it clear by regulation, that the addition of acute care beds in outpatient locations is, by definition, the creation of a new hospital, which requires a new original license and by statute, the establishment of a new hospital requires DoN action and review by the Public Health Council. So if any hospital were to add beds at a satellite outpatient location that would constitute the creation of a new hospital, resulting in the requirement for a DoN and subsequent Public Health Council action...the next provision is to establish a sunset provision for unused physician exemption letters that bypass the DoN process. The third item is to modify the .308 process in which we currently allow hospitals acquisition of MRIs. Discussion followed; please see the verbatim transcript for the full discussion. Drs. Zuckerman, Woodward, Gillick and Rosenthal commented on the need for a broader discussion on the health care delivery system in Massachusetts and perhaps nationally, including what should be the Determination of Need Program's role. Dr. Rosenthal noted that DoN

didn't seem to be impacting ambulatory services, the profitable place. Dr. Dreyer responded by noting that the problem is that ambulatory services are not regulated except for innovative services and new technology – a statutory change would be necessary to address ambulatory conditions. Chair Auerbach pointed out that in the last twenty years; a lot of services that were done as an inpatient service have now become an outpatient service so at that point in time the Legislature couldn't address the issue through DoN. Council Member Lanzikos added that he "hopes the administration and Legislature have some sense of a whole system before they start making corrective actions among the pieces because one would not want to create a new set of unimagined issues..." Chair Auerbach stated that he heard that the Council would like to have the broader health care delivery discussion at a future meeting of the Council and further that the Council would favor participating in planning processes outside the formal Council meetings and take the initiative of bringing people together to discuss the issue. Discussion continued.

In closing staff said, "These enhancements will strengthen the ability of the Department to oversee the expansion of inpatient hospital services into new markets, end the practice of marketing physician exemption letters, and require community initiative contributions when 308 exemptions are granted. Staff will hold a public hearing and return to the Council to report on testimony and any recommended changes to these proposals."

### **No Vote/Information Only**

### **DETERMINATION OF NEED PROGRAM:**

#### **Determination of Need Compliance Memorandum: Approved DoN Project No. 3-3A95, BRN Corporation – Transfer of Ownership of an Unimplemented DoN:**

Ms. Joan Gorga, Director, Determination of Need Program, presented the BRN Corporation request to the Council. Staff's analysis indicated, "The transfer of ownership of the unimplemented project presently under construction would be accomplished by a transfer of 100% of the stock in BRN Corporation from Dr. Arcidi to his three sons."

Staff further noted in the memorandum to the Council, dated April 9, 2008, "The financial resources of the transferees are capable of funding the project because the construction loan continues to be in the name of Bradford Rehabilitation Associates Limited Partnership and BRN Corporation and is personally guaranteed by Dr. Alfred Arcidi. The lender, a bank, has agreed that the proposed change in the ownership of the BRN Corporation will not affect the terms of the loan. The transferees will have access to the same financial

resources as identified in the original application for the timely completion of the project. Staff noted that the original transfer of ownership submission from the holder in December 2007 indicated that construction began on the project in July 2007, that approximately \$5,202,979 had been incurred in the construction and renovation of the project, and that the project was approximately six (6) months from completion. More recent information from the holder indicates that the project is now over 70% complete. The original transfer of ownership submission listed nine other health care facilities within Whittier Health Network. The BRN Corporation is the tenth. Dr. Arcidi presently serves as President and Director of each entity. Management and operations of the facilities are in the hands of his three sons of whom holds positions of authority and responsibility in each of the entities and who collectively control their boards of directors..."

Staff found that the holder met the regulatory Standard of Review referenced under DoN Regulation 105 CMR 100.710 (A) (7) and 105 CMR 100.710 (A)(8). Comments opposing the transfer of ownership were submitted by the Mark R. Taylor Interested Party. The TTG asked questions on the following issues: project financing and feasibility, HUD financing, financial capabilities of the proposed transferees, sufficient interest in site, compliance with 105 CMR 100.710 and lack of notice to the original TTG, themselves.

Staff's memorandum to the Council outlines their response to the TTG questions. Their response said in part, "...The holder indicates that the transfer will not affect the manner of the financing for the project which is being accomplished through the owner of the property, Bradford Rehab Associates Limited Partnership ("Bradford") and the holder of the DoN and lessee of the property, BRN Corporation with a personal guarantee of Dr. Arcidi. BRN is the general partner of Bradford and Dr. Arcidi and his sons are the limited partners. The owners have contributed over \$1,000,000 in equity to date with the project over 70% complete and the balance of the cash equity requirement will be satisfied as the construction work is completed. In addition the property has been appraised for \$1,829,000 more than the original purchase price therefore effectively increasing the equity contribution of the owners."

"The proposed transfer will not affect the project financing. The construction financing has been through a bank and the permanent financing will be either through a bank or through a HUD-insured lender as originally proposed. The costs are consistent with the original DoN and if there are any changes the holder will file as necessary with the Department. The holder has indicated that the project will proceed regardless of whether the proposed transfer takes place. The transfer is based entirely on the estate planning of Dr. Arcidi. The transfer has not taken place and is awaiting the approval of the Department...Bradford will lease the property to BRN for an initial term of ten years with three five-year options to extend as stated in the original application. These terms meet the



requirements for site control under 105 CMR 100.306. The transfer request submitted in December 2007 was signed by an attorney, since that submission, the information submitted by Dr. Arcidi has included the statement that it was signed under pains and penalties of perjury and, in addition, an affidavit of truthfulness and proper submission for the transfer has been signed, notarized and submitted to the Department. The holder has also submitted a Declaration of Gift of Stock which sets forth the terms of the transfer and has been signed by Dr. Arcidi. Any standing that the Mark Taylor TTG had ended with approval of the original application, therefore the holder was not required to notify the TTG of this transfer of ownership application. However, the BRN Corp. published notice of the transfer in the newspaper and the TTG submitted comments in response to that notice.

Staff recommended approval of the transfer of ownership. Dr. Alan Woodward made the motion for approval. After consideration, upon motion made and duly seconded, it was voted unanimously [Dr. Barry Zuckerman was not present to vote] to approve the **Request of Approved DoN Project No. 3-3A95 of BRN Corporation for Transfer of Ownership of an Unimplemented DoN**, resulting from a transfer of 100% of the shares of stock in BRN Corporation from Dr. Alfred Arcidi to his three sons, Alfred J. Arcidi, Philip M. Arcidi and Michael Arcidi. The reason for this approval is that the applicant satisfies the requirements of the transfer of ownership standards found in DoN Regulations 105 CMR 710.000.

## **CATEGORY 2 APPLICATIONS:**

### **Project Application No. 5-4925 of Cape Cod/Taunton PET/CT Services**

for establishment of mobile Positron Emission Tomography/Computerized Axial Tomography (PET/CT) service through a consortium of joint ventures associated with Cape Cod Hospital, Falmouth Hospital, and Morton Hospital to provide services at two sites, Harwich and Taunton.

### **Project Application No. 2-3B34 of Milford Regional Medical Center, Inc.**

for acquisition of a mobile PET/CT scanner and operation of a PET/CT service 3.5 days per week on its main campus in Milford.

Mr. Bernard Plovnick, Consulting Analyst, Determination of Need Program, presented the applications to the Council. Mr. Plovnick provided the following information to the Council (See staff summaries for full staff analysis):

“Cape Cod PET-CT Services LLC and Taunton PET-CT Services LLC have filed a DoN to establish a mobile Positron Emission Tomography (PET) service through acquisition of a combination mobile PET/CT unit to provide services in Harwich and Taunton. Three hospitals have formed a consortium (Cape Cod Hospital,

Falmouth Hospital and Morton Hospital) along with Shields Healthcare for providing PET services at two separately licensed clinics to be located at Cape Cod Healthcare's Fontaine Medical Center, 525 Long Pond Drive in Harwich and at Morton Hospital at 88 Washington Street, Taunton. According to the applicant, the application was filed to improve the delivery of PET services to patients and the consortium was formed because none of the participating hospitals have sufficient volume to support their own service. If approved, the new service would replace a contract with a PET services provider currently leasing space from one of the consortium members and operating under a DoN Physician exemption. According to the applicant, the current service is limited and not well integrated into the members' organizational and information systems. The proposed maximum capital expenditure of \$3,066,500 (February 2007 dollars) is comprised of the cost of mobile PET/CT scanner and the fair market value of space, including existing technology docking space, to be leased from consortium members. There is no construction associated with this proposed project."

Mr. Plovnick further noted that the applications were reviewed in accordance with the November 24, 1998 Determination of Need Guidelines for Positron Emission Tomography. The Guidelines do not recommend a statewide planning target of a specific number of PET units, but require each applicant to demonstrate a projected minimum demand of 1,250 annual scans in the service area...Cape Cod/Taunton PET could demonstrate a total of 1,583 and 1,620 PET and PET/CT scans in 2006 and 2007, which exceeds the Guidelines minimum volume requirement (estimated cancer and cardiac perfusion scans). Milford Regional does not plan to use the PET/CT scanner for cardiac perfusion patients. To estimate the demand for the scans, staff has applied a diagnosis specific standard rate of PET scans per 1,000 patients (based on actual 2004 Massachusetts General Hospital PET scan utilization) to the actual calendar year of 2006 cancer volume submitted by Milford Regional, which indicates an estimated demand for 852 and 923 cancer PET scans in calendar years 2006 and 2007 for Milford Regional...Staff finds need for the PET/CT unit operating 3.5 days per week, as proposed by Milford Regional...Staff finds based upon data submitted by the applicant, the estimated utilization for the proposed PET/CT scanner exceeds the minimum annual volume required by the Guidelines of 1,250 scans, prorated to 875 annual scans for a schedule of 3.5 days of operating per week."

The staff summary states, "Cape Cod/Taunton PET has proposed to acquire a PET/CT scanner which has received pre-market approval by the Food and Drug Administration for commercial use. The combined machine, which currently represents the state of the art in PET scanning, uses the capabilities of both diagnostic tools. The CT can detect masses in the body, but cannot determine if they are cancerous, while the PET can detect cancerous cells, but cannot exactly

pinpoint their location. The current medical literature indicates that the fusion and correlation of these two imaging modalities has been shown to result in improved surgical planning, assessments, a substantial majority of patients in the service areas of the consortium hospitals will benefit by having a CT scan at the same time as a PET scan."

Discussion followed by the Council. Some Council members had questions on quality and costs of the PET/CT Services proposed. The Council wondered about the cost difference, Milford Regional Medical Center was seeking a maximum capital expenditure of \$1,200,000 and Cape Cod/Taunton PET was seeking \$3,066,500 in MCE. Staff explained that Milford would be operating only part-time (3.5 days per week) and Cape Cod/Taunton PET would be operating full-time (7 days per week) and that Milford was a fixed unit and the Cape Cod/Taunton project would be a mobile service, requiring construction of pads. Staff did not compare the two separate projects in its analysis but rather looks at the institutions own case mix data and projected number of procedures. Chair Auerbach said the Council had three choices: (1) they could approve both applications as recommended by staff; (2) approve one or the other; or (3) go back to the Determination of Need Program for more information before they vote. Dr. Gillick noted on the other hand, "I'm not concerned about discrepancies in costs...Pet Scanners are supply sensitive..."

Dr. Muriel Gillick made the motion to approve the application. After consideration, upon motion made and duly seconded it was voted unanimously to approve **Project Application No. 5-4925 of Cape Cod PET-CT Services LLC and Taunton PET/CT Services LLC**, with a maximum capital expenditure of \$3,066,500 (February 2007 dollars) and \$2,422,555 (February 2007 dollars) for first year incremental operating costs. A staff summary is attached and made a part of this record as **Exhibit No. 14,900**. As approved, this application provides for establishment of a mobile PET/CT scanner, which will serve patients of Cape Cod Hospital, Falmouth Hospital, and Morton Hospital from service locations in Harwich and Taunton. This Determination of Need is subject to the following conditions:

1. Cape Cod/Taunton PET shall accept the maximum capital expenditure of \$3,066,550 (February 2007 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.
2. Cape Cod/Taunton PET shall not consider ability to pay or insurance status in selecting or scheduling patients for PET/CT services.
3. Prior to licensure of a PET/CT service, Cape Cod/Taunton PET shall submit to the DoN Program Director documentation of an affiliation agreement

with a tertiary medical center.

4. Cape Cod/Taunton PET shall submit to the DoN Program Director documentation of the clinical oversight activities of its PET/CT clinical oversight committee for a period of two years following the date of project approval.
5. Cape Cod/Taunton PET shall provide to a fiscal agent the full \$153,325 to be distributed equally over a five year period to the Greater Attleboro-Taunton Health Education ("CHNA 24") and the Cape Cod and Islands Health Network ("CHNA 27") in annual payment of \$15,333 each to be used in support of its activities as follows:
  - a. Mini-grants awarded through an open, competitive request for responses (RFR) with preference given to projects and/or activities that are science-based, directed by healthy communities' principles with priority given to eliminating health disparities. Each program that receives funding to achieve the identified priorities will be required to conduct and report an annual evaluation. Upon receiving these funds, the CHNAs will submit a detailed budget to the Office of Healthy Communities (OHC) and yearly thereafter. The CHNAs will annually submit to the OHC, with a copy to Cape Cod/Taunton PET, a summary report of program activities for the prior year, including funding against budget and measured outcomes of program activities. The CHNA and the OHC may reassess need and funding priorities periodically; and
  - b. General community capacity building and program support and staffing including, but not limited to, coalition coordination, training programs and networking opportunities and program evaluation that promote and build on a healthy communities/health disparities framework.
6. With regards to its interpreter service:
  - a. Cape Cod/Taunton PET shall post signage at all points of contact and public points of entry informing patients of the availability of interpreter services at no charge.
  - b. Policies and procedures at all Cape Cod/Taunton PET sites shall stipulate that trained interpreters, including center staff, will be used exclusively to provide medical interpretation and/or logistical support.

- c. Cape Cod/Taunton PET shall develop a reliable and valid system to schedule, track requests and monitor completed interpreting sessions, inclusive of the employee interpreters.
- d. Cape Cod/Taunton PET shall develop a plan to assess the quality of Interpreter Services and monitor the competence of interpreters, inclusive of employees.
- e. Cape Cod/Taunton PET shall continue to assess and revise the plan for training clinical and support administrative staff on the appropriate use of interpreter services, inclusive of telephonic services.
- f. Cape Cod/Taunton PET shall continue to ensure timely, accurate, competent, and culturally appropriate patient educational materials. The guidelines developed by OHE on translating materials are a recommended source for translating patient materials.
- g. Cape Cod/Taunton PET shall develop a plan to ensure the inclusion of LEP patients in patient satisfaction surveys.
- h. Cape Cod/Taunton PET shall follow recommended National Standards for Culturally and Linguistically Appropriate Services (CLAS) in Health Care (materials available online at <http://www.omhrc.gov/templates/browse.aspx?1v1=2&1v1ID=15>).
- i. Cape Cod/Taunton PET shall submit annual progress reports to OHE within 45 days following the end of each federal fiscal year.
- j. Cape Cod/Taunton PET shall undertake a yearly Language Needs Assessment (LNA). (Guiding principles developed by OHE are a recommended source).
- k. Cape Cod/Taunton PET shall identify how patient data collected on race and ethnicity will be used to improve patient care and to eliminate health disparities.
- l. Cape Cod/Taunton PET shall include the Director of interpreter Services in all decision-making processes having an impact on LEP patients.
- m. Cape Cod/Taunton PET shall notify OHE of any substantial changes to its interpreter services program.

- n. Within 45 days following DoN Approval, Cape Cod/Taunton PET shall submit to OHE a plan for improvement, addressing the above items.

Staff's recommendation was based on the following findings:

1. Cape Cod/Taunton PET proposes to establish a mobile PET/CT service that will provide services at Harwich and Taunton through a consortium of hospital affiliated joint ventures associated with Cape Cod Hospital, Falmouth Hospital, and Morton Hospital.
2. The project meets the requirements of the health planning process consistent with the Guidelines.
3. Cape Cod/Taunton PET has demonstrated demand for the proposed PET/CT service, as discussed under the Health Care Requirements factor of the Staff Summary.
4. The project, with adherence to a certain condition, meets the operational objectives of the Guidelines.
5. The project meets the compliance standards of the Guidelines.
6. The recommended maximum capital expenditure of \$3,066,550 (February 2007 dollars) is reasonable, based on a similar, previously approved projects.
7. The recommended incremental operating costs of \$2,422,555 (February 2007 dollars) are reasonable for a mobile PET/CT service.
8. The project is financially feasible and within the financial capability of the applicant.
9. The project meets the relative merit provisions of the Guidelines.
10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.
11. The Donald O'Leary Ten Taxpayer Group registered in connection with the proposed project, but did not submit written comments or request a public hearing.
12. This project is one of two comparable applications along with Project #2-3B34 filed by Milford Regional Medical Center. When considered alone,

each application is capable of being approved, since each has demonstrated demand for PET/CT services. A detailed comparability analysis was not undertaken since these two applications each meet all of the review factors of the Guidelines.

Mr. Albert Sherman made the motion to approve the application. After consideration, upon motion made and duly seconded it was voted unanimously to approve **Project Application No. 2-3B34 of Milford Regional Medical Center, Inc.,** with a maximum capital expenditure of \$1,200,000 (February 2007 dollars) and \$1,030,855 (February 2007 dollars) for first year incremental operating costs. A staff summary is attached and made a part of this record as **Exhibit No. 14,901.** As approved, this application provides for establishment of a mobile PET/CT service that will operate up to 3.5 days per week (70% of full capacity) on its campus at 14 Prospect Street, Milford, MA 01757. This Determination of Need is subject to the following conditions:

1. Milford Regional shall accept the maximum capital expenditure of \$1,200,000 (February 2007 dollars) as the final cost figure, except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.
2. Milford Regional shall not consider ability to pay or insurance status in selecting or scheduling patients for PET/CT services.
3. Milford Regional shall contribute \$12,000 annually for a period of 5 years, a total of \$60,000, or 5% of the maximum capital expenditure for this project to fund community health initiatives in the Milford area. Milford Regional shall work with CHNA 6 to design community health programs consistent with the area's targeted health priorities based on the community assessment and strategic planning process based on the healthy communities' principles to be conducted in 2008 by CHNA 6. The programming can include, but is not limited to: 1) an annual conference on an identified health concern; (2) health promotion campaigns targeted at the schools and the community at large; and (3) mini-grants to local agencies. A portion of the funds will be allocated to CHNA program support and evaluation of the programs undertaken.

Milford Regional and CHNA 6 shall provide the Office of Healthy Communities with yearly reports regarding community health initiatives undertaken including detailed budgets and program outcomes. CHNA 6 will determine the fiscal agent for the funds.

Staff's recommendation was based on the following findings:

1. Milford Regional proposes to establish a PET service through acquisition of a mobile combination PET/CT scanner that will operate up to 3.5 days per week (70% of full capacity) on its campus at 14 Prospect Street, Milford, MA 01757.
2. The project meets the requirements of the health planning process consistent with the Guidelines for Positron Emission Tomography.
3. Milford Regional has demonstrated demand for the proposed PET/CT service, as discussed under the Health Care Requirements factor of the Staff Summary.
4. The project meets the operational objectives of the Guidelines.
5. The project meets the compliance standards of the Guidelines.
6. The recommended MCE of \$1,200,000 (February 2007 dollars) is reasonable, based on similar, previously approved projects.
7. The recommended incremental costs of \$1,030,855 (February 2007 dollars) are reasonable for a mobile PET/CT unit, based on similar, previously approved projects.
8. The project is financially feasible and within the financial capability of the applicant.
9. The project reasonably meets the relative merit provisions of the Guidelines.
10. The project, with adherence to a certain condition, meets the community health service initiatives of the DoN Regulations.
11. This project is one of two comparable applications along with Project #5-4925 filed by Cape Cod PET-CT Services LLC and Taunton PET-CT Services LLC. When considered separately, each application is capable of being approved, since each has demonstrated sufficient demand for PET/CT. A detailed comparability analysis was not undertaken since the two applications each meet all of the review factors of the PET Guidelines.

**Note:** Council Member Sherman left the meeting here at the start of the Edgewood Retirement Community application.



**Project Application No. 3-1504 of Edgewood Retirement Community, Inc. for new construction to add four new Level II skilled nursing (SNF) beds and replace and relocate 15 existing Level II beds at the existing 45-bed Level II Skilled Nursing Facility (SNF) known as the Meadows, which is part of the existing 219-resident unit Continuing Care Retirement Community called the Edgewood Retirement Community located at 575 Osgood Street in North Andover, MA. The project also involves renovation of 30 existing Level II beds:**

Mr. Jere Page, Senior Analyst, Determination of Need Program, presented the application to the Council, followed by a brief discussion by the Council. Ms. Marlene Roterling, the applicant, answered a couple of brief questions from the Council regarding having no escrow agent, which is addressed in a condition of approval, and she also confirmed that Edgewood was not in the Medicaid program since 1998. Council Member Paul Lanzikos has several concerns and recommendations. One was in regard to the Health planning process. He suggested that more community based resources should be consulted by DoN Applicants such as the State Office of Elder Affairs, Aging and Disabilities, and the Mass. Rehabilitation Commission.

Staff's summary to the Council states in part, "Continuing Care Retirement Communities (CCRCs) are residential complexes that feature care and support services for the residents. The great majority of CCRCs actually have a nursing home within the complex, and many have physician offices and home health services. The resident has a contract with the CCRC sponsor that specifies the sponsor's obligations, which include medical and support services. The contract is, in effect, an insurance policy in which the individual purchases a package of residential and health care services, and the sponsor uses the combined entrance fees and payments to meet the needs of the members of the community..."

Staff indicated, "According to the CCRC Guidelines, Type A CCRC nursing home beds are exempt from the nursing home bed need projections in the Determination of Need ("DoN") Long Term Care Bed Guidelines. In the absence of other review factors for nursing home beds in the CCRC Guidelines, the more recent Determination of Need Guidelines for Nursing Facility Replacement and Renovation ("Nursing Facility Guidelines") were used in the review of this project."

Mr. Page further noted, "That the applicant consulted with staff from the Executive Office of Elder Affairs and the DoN Office regarding the standards, criteria and guidelines for construction of long term care facilities in Massachusetts. Edgewood also consulted with other providers in the area including Lowell General Hospital, the Merrimack Valley Hospice, and Prescott House. Staff found that the applicant engaged in a satisfactory health planning

process. Edgewood has in place signed transfer agreements with a local acute care hospital and local home health provider..."

It was noted that Edgewood is proposing a total of 29,577 gross square feet (GSF) which Edgewood may construct at its own risk, including: 8,636 GSF for new construction to add 4 new Level II beds and replace 15 existing Level II beds; 15,896 GSF for substantial renovation of 30 existing Level II beds; and 5,045 GSF for 11 Level II exempt beds available under 105 CMR 100.020, definitions of Expansion and Substantial Change in Services of the DoN Regulations. The requested and recommended MCE for the proposed Edgewood new construction and renovation is \$8,268,000 (November 2007 dollars). This is a construction costs per gross square foot (GSF) of \$453.00 which is higher than what is allowed by the Marshall and Swift Valuation Service rate of \$260.34 cost/GSF in the North Andover area. However, since this rate is for calculating Medicaid rates and this project is not eligible for Medicaid reimbursement (it is privately funded) the recommended MCE shall be at Edgewood's own risk."

Dr. Muriel Gillick made the motion to approve the application. After consideration, upon motion made and duly seconded it was voted unanimously [Mr. Sherman not present] to approve **Project Application No. 3-1504 of Edgewood Retirement Community, Inc. (CCRC)**, with a maximum capital expenditure of \$8,268,000 (November 2007 dollars) and \$3,376,988, (November 2007 dollars) for first year incremental operating costs. A staff summary is attached and made a part of this record as **Exhibit No. 14,902**. As approved, this application provides for new construction to add four new Level II skilled nursing (SNF) beds and replace and relocate 15 existing Level II beds at the existing 45-bed Level II Skilled Nursing Facility "SNF" known as the Meadows, which is part of the existing 219-resident unit Continuing Care Retirement Community called the Edgewood Retirement Community located at 575 Osgood Street in North Andover, MA. The project also involves renovation of 30 existing Level II beds. Edgewood also proposes to add 11 Level II beds as a one-time expansion available under 105 CMR 100.020, definitions of Expansion and Substantial Change in Services of the DoN Regulations. This approval is subject to the conditions listed below. Edgewood has agreed to these conditions. Failure of the applicant to comply with these conditions may result in Departmental sanctions including possible fines and/or revocation of the DoN. This Determination is subject to the following conditions:

1. Edgewood shall not admit Medicaid patients or seek Medicaid funds for residents of the CCRC. Edgewood Retirement Community, as a Type "A" CCRC long term care facility granted Unique Application status, is precluded from accepting Medicaid patients.

2. Edgewood shall accept the maximum capital expenditure of \$8,268,000 (November 2007 dollars) as the final cost figure except for those increases allowed pursuant to 105 CMR 100.751 and 100.752.
3. Edgewood shall not commence construction of its 4 new skilled nursing home beds until 11 of the residential care units have been presold.
4. Edgewood shall comply with the existing residency agreement/contract submitted to the Determination of Need Office on November 29, 2007, which meets the contractual requirement criteria to qualify as a "Type A" CCRC facility.
5. The total approved gross square feet (GSF) for this project is 29,577 GSF: 8,636 GSF for new construction to accommodate 4 new Level II beds and 15 replacement beds; 15,896 GSF for substantial renovation of 30 existing Level II beds; and 5,045 GSF for 11 Level II exempt beds available under 105 CMR 100.020, definitions of Expansion and Substantial Change in Services of the DoN Regulations.
6. Edgewood shall obtain Medicare certification for its Level II beds.
7. Prior to commencing construction of the proposed CCRC, Edgewood shall submit documentation of maintenance of restricted reserve funds to cover debt service, refunds and facility operations, as well as documentation that a Massachusetts escrow agent has been selected for entrance fees and deposits.
8. Edgewood shall adhere to the terms of 105 CMR 100.552(B) by filing a progress report regarding compliance with the above conditions with the DoN Program once within two years after implementation of this project. The report shall be filed annually thereafter.

Staff's recommendation was based on the following findings:

1. Edgewood Retirement Community, Inc. is proposing new construction to add 4 new Level II skilled nursing (SNF) beds and replace and relocate 15 existing SNF beds at the existing 45-bed Level II Skilled Nursing Facility (SNF) known as the Meadows, which is part of the existing 219-resident unit Continuing Care Retirement Community called the Edgewood Retirement Community located at 575 Osgood Street in North Andover, MA. The project also involves renovation of 30 existing Level II beds. Edgewood also proposes to add 11 Level II beds as a one-time expansion available under 105 CMR 100.020, definitions of Expansion and Substantial Change in Services of the DoN

Regulations. The project, when completed, will serve only the residents of the CCRC.

2. The application was filed as an unique application pursuant to 105 CMR 100.302 (B) of the Determination of Need regulations because as a Type A CCRC Level II bed nursing home, it will only be open to residents of the CCRC, and will be supported entirely by private funds.
3. The health planning process for this project was satisfactory.
4. The proposed Edgewood project qualifies as a Type A facility under the Continuing Care Retirement Community Guidelines. Therefore, the 4 new Level II beds associated with this facility are exempt from the nursing home bed need projections, which show a surplus of existing beds through the year 2010, resulting in a moratorium on the construction of new nursing home beds until 2010, voted by the Public Health Council at its meeting on January 26, 2006, as discussed under the health care requirements of the staff summary.
5. The project, with adherence to certain conditions, meets the operational objectives of the nursing home Facility Guidelines.
6. The project, with adherence to a certain condition, meets the standard compliance factor of the Nursing Facility Guidelines.
7. The recommended maximum capital expenditure (MCE) of \$8,268,000 (November 2007 dollars) is reasonable, assuming no Medicaid reimbursement.
8. The estimated operating costs of \$1,525,770\* (November 2007 dollars) for the project's first full year of operation (FY2010) are reasonable, assuming no Medicaid reimbursement.
9. The project is financially feasible and within the financial capability of the applicant.
10. The project meets the relative merit requirements of the Nursing Facility Guidelines.
11. The project is exempt from the community health initiatives of the DoN Regulations.
12. The Division of Health Care Finance and Policy (DHCFP) did not submit comments on the proposed project regarding MassHealth

reimbursement for capital costs, as no Medicaid reimbursement will be sought for the project's nursing home patients.

13. The Executive Office of Elder Affairs (EOEA) submitted no comments on the proposed project.

14. The Division of Medical Assistance submitted no comments on the proposed project.

\*amount corrected at the PHC meeting

**"Massachusetts Death Profile, 2006", by Isabel Cáceres, Epidemiologist, Division of Research and Epidemiology, Bureau of Health Information, Statistics, Research:**

Ms. Isabel Cáceres, Epidemiologist, the DPH Division of Research and Epidemiology made a Powerpoint slide presentation to the Council. She answered a few brief questions by the Council. Some statistics from her presentation follow:

- The Massachusetts death rate was the lowest on record
- Massachusetts compared favorably to the U.S.
- Life expectancy reached a record high
- Cancer is the leading cause of mortality in MA
- Cancer and heart disease death rates continued to decline
- Increase in poisonings and fall deaths in 2006
- Two out of 3 poisoning deaths are related to opioids
- Increasing trend in homicide rates
- Disparities persist by:
  - gender
  - race and ethnicity
  - education
  - geography

For further information see the DPH web pages at <http://mass.gov/dph/resep> or <http://masschip.state.ma.us>.

**No Vote/Information Only**

**Note for the record**, Council Member Dr. Barry Zuckerman left the meeting during the Deaths 2006 Presentation at approximately 11:50 a.m. Dr. Michele David and Mr. Denis Leary left the meeting prior to the last item below, the Informational Briefing on Proposed Amendments to Reportable Disease, Isolation & Quarantine Regulations – 105 CMR 300.000

**PROPOSED REGULATION: INFORMATIONAL BRIEFING ON PROPOSED AMENDMENTS TO REPORTABLE DISEASE, ISOLATION & QUARANTINE REGULATIONS – 105 CMR 300.000:**

Dr. Alfred DeMaria, Director, Bureau of Communicable Disease Control and Ms. Gillian A. Haney, MPH, Director, Office of Integrated Surveillance and Information Services, Bureau of Communicable Disease Control presented the Proposed amendments to 105 CMR 300.000 to the Council.

Dr. DeMaria made introductory remarks, thanking Dr. Michael Wong, Public Health Council Member, Attorney Susan Stein, First Deputy General Counsel for DPH and Attorney Priscilla Fox, Consulting Attorney for DPH for their input, suggestions, and work on the regulations.

Ms. Gillian Haney presented the proposed changes to the Council and answered a few questions by the Council. Staff's memorandum to the Council states, "The purpose of the proposed amendments is to update the regulations by incorporating new federal communicable disease surveillance recommendations and the latest recommendations for isolation and quarantine. A number of diseases, as well as clarification of some of the reportable events, will be added to the list of diseases dangerous to the public health in order to reflect emerging infectious disease threats, changes in nomenclature and newly recognized disease presentations. New sections to be added include the following: clarification of specimens to be submitted to the State Laboratory Institute for further examination, clarification of the legal procedures necessary to implement isolation and quarantine measures, and a requirement for laboratories to report to the Department via specified electronic means."

Proposed Revisions to the regulations are summarized below:

1. 105 CMR 300.020: Definitions. The following terms were defined or further clarified: (a) Board of Health or Local Board of Health (b) Food Handler, and (c) Food Handling Facility.

Food Handling Facility Employee was removed.

2. 105 CMR 300.100: Diseases Reportable to Local Boards of Health. Anaplasmosis, Chagas disease, variant Creutzfeld-Jakob disease, noroviruses, and vibriosis (non-Cholera) have been added to the list of diseases reportable by health care providers. Calicivirus infection and Guillain Barré syndrome were removed from the list of diseases reportable

by health care providers.

3. 105 CMR 300.130: Prevention of Foodborne Cases of Viral Gastroenteritis. This section was removed from the regulations and incorporated into specific isolation and quarantine requirements in section 300.200
4. 105 CMR 300.135: Reporting of Pediatric Influenza Deaths and Illness Believed to be Due to Novel Influenza viruses. This new section requires health care providers to report directly to the Department, within 24 hours suspect and confirmed deaths due to influenza in pediatric patients and suspect and confirmed cases of influenza A viruses different from those human H1 and H3 viruses currently circulating
5. 105 CMR 300.140: Reporting of Animal Disease with Zoonotic Potential by Veterinarians. The language in this section was clarified
6. 105 CMR 300.170: Laboratory Findings Indicative of Infectious Disease Reportable Directly to the Department by Laboratories. Laboratories are required to report directly to the Department through secure electronic laboratory reporting mechanisms or other method as defined by the Department. The list of laboratory findings was also updated to correspond with all diseases listed in 105 CMR 300.100. *Anaplasma* sp., *Bordetella bronchiseptica*, *Bordetella holmseii*, *Bordetella parapertussis*, *Clostridium difficile*, noroviruses, novel influenza A viruses and *Trypanosoma cruzi* were added to the list
7. 105 CMR 300.171: Reporting of Antimicrobial Resistant Organisms. Invasive methicillin-resistant *Staphylococcus aureus* (MRSA) was added to the list
8. 105 CMR 300.172: Submission of Selected Isolates and Diagnostic Specimens to the State Laboratory Institute. This new section specifies the specific isolates and specimens that must be submitted to the State Laboratory Institute for further examination.
9. 105 CMR 300.200: Isolation and Quarantine Requirements (A) Diseases Reportable to Local Boards of Health. Some of the proposed revisions are as follows: add Anaplasmosis, Chagas Disease (American trypanosomiasis), *Clostridium difficile*, Vibriosis (non-cholera), to the list reportable to Local Boards of Health. Remove phrase "handling facility employees" in many places on the list and various other clarifications. Please see proposed regulations for further information

10. 105 CMR 300.200: Isolation and Quarantine Requirements B) Reportable Directly to the Department (see a copy of the proposed regulations for minor changes)
11. 105 CMR 300.210: Procedures for Isolation and Quarantine. This section specifies detailed procedures, including due process protections for people subject to an order of isolation or quarantine, that the agency issuing such an order should follow. The procedures are mandatory for MDPH, but “encouraged” for local health agencies because these agencies have independent authority to issue their own isolation/quarantine regulations under G.L.c.111, s.31. At least one municipality (Boston) has done this.

Due to process protections, including provisions for appeal of an order, are important and constitutionally required in situations of isolation and quarantine. MDPH has been giving training programs to local health officials for several years about these requirements, but they have never before been incorporated into regulations. Specifying these requirements clearly in regulations will be of great help to local health agencies. It should also be noted that subsection 300.210(H), “Requirements for Isolation or Quarantine” (governing matters like maintenance of isolation/quarantine premises, etc.) is adapted from the Model Emergency Health Powers Act drafted by the Georgetown and Johns Hopkins Center for Law and the Public Health in 2001. Provisions like these were originally included in a bill filed in the Massachusetts legislature several years ago. MDPH believes that these provisions are more appropriate in regulations rather than statute, so upon our request they have been withdrawn from subsequent versions of the bill and are now included in these draft regulations.

### **No Vote/Information Only**

The meeting adjourned at 12:15 p.m.

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John Auerbach, Chair

LMH